STATE OF MICHIGAN

DEPARTMENT OF LABOR & ECONOMIC GROWTH

OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX
Petitioner **File No. 89453-001**
v

Blue Cross Blue Shield of Michigan
Respondent
_____/

Issued and entered
This 3rd day of July 2008
by Ken Ross
Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On April 28, 2008, XXXXX, authorized representative of XXXXX (Petitioner), filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 *et seq*. The Commissioner reviewed the material submitted and accepted the request on May 5, 2008.

Because it involved medical issues the Commissioner assigned the case to an independent review organization (IRO), which provided its analysis and recommendations to the Commissioner on May 19, 2008.

II
FACTUAL BACKGROUND

The Petitioner receives health care benefits from Blue Cross Blue Shield of Michigan (BCBSM) under its Non-Group Comprehensive Health Care Benefit Certificate (the certificate).

The Petitioner requested preauthorization for a cervical disc replacement using the Prestige Cervical Disc replacement device. BCBSM denied preauthorization of this procedure because it is considered experimental or investigational for treatment of the Petitioner's condition.

The Petitioner appealed BCBSM's denial. After a managerial-level conference on April 14, 2008, BCBSM did not change its decision and issued a final adverse determination dated April 16, 2008.

III
ISSUE

Did BCBSM properly deny preauthorization for the Petitioner's cervical disc replacement surgery?

IV
ANALYSIS

Petitioner's Argument

The Petitioner believes BCBSM was wrong to deny preauthorization for the Prestige Cervical Disc replacement surgery on the basis that it is considered experimental. She says the device was approved by the Food and Drug Administration in 2007, is covered by many insurance carriers, and has been approved for use by some government agencies.

The Petitioner has had two neck surgeries in the past in the same area, discs C5 to C7. The Petitioner had profound spinal stenosis that required a two level anterior fusion and decompression and then a posterior laminoplasty and fusion. Her surgeon does not recommend additional fusion because it would severely limit her range of motion, thus limiting her quality of life and ability to work.

The Petitioner's doctors believe that the Prestige Cervical Disc replacement surgery is a much better option. It has a "ball and trough" feature which allows about 7 degrees of motion per disc replacement (similar to a normal healthy disc). According to the Petitioner, the procedure is also less expensive, faster, and has a shorter recovery time.

The Petitioner does not believe this procedure is experimental for treatment of her condition and she believes that BCBSM is required to preauthorize and pay for it.

BCBSM's Argument

The certificate, on page 6.9, defines "Experimental Treatment" as:

> Treatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment. Sometimes it is referred to as "experimental services."

The certificate, on pages 3.17 - 3.18, contains the following exclusion from coverage:

> **The following services are not payable**:
>
> * * *
>
> - Experimental treatment

BCBSM's medical director determined that the artificial intervertebral disc replacement requested by the Petitioner is experimental -- it has not been scientifically demonstrated to be better than currently available lumbar fusion procedures. BCBSM therefore believes that it is not required to cover the Petitioner's requested surgery under the terms of her coverage.

Commissioner's Review

The certificate sets forth the benefits that are covered. A procedure that is not accepted as the standard of care and has not been demonstrated to be as safe and effective as conventional or standard treatment is considered to be investigational or experimental and is not a covered benefit under the terms of the Petitioner's coverage.

The question of whether the Petitioner's proposed artificial intervertebral disc replacement surgery is considered experimental or investigational for treatment of her condition was presented to an IRO for analysis as required by section 11(6) of PRIRA, MCL 550.1911(6). The IRO physician reviewer is certified by the American Board of Orthopedic Surgery, is a graduate of a fellowship training program in spine surgery, and is in active clinical practice.

The IRO physician reviewed the relevant documentation provided including the medical records and health plan correspondence. The IRO's report states:

> [T]he first therapeutic approach in such cases and the standard of care usually consists of anti-inflammatory medications as well as physical therapy and home exercise programs. From the records, it appears that all these interventions failed [the Petitioner], which resulted in the recommendation of the proposed surgical procedure. In addition, the Petitioner had undergone posterior laminoplasty and fusion.
>
> In the opinion of the Reviewer, the artificial cervical total disc replacement is appropriate and medically necessary in this patient who continues to have spinal stenosis as well as painful neurological symptoms and failed prior spinal fusions. Further the Reviewer stated that cervical total disc replacement is not only approved by the Food and Drug Administration (FDA), but is no longer considered experimental or investigational in the orthopedic spinal surgery community. North American Spine Society (NASS), European Spine Society (ESS) and professional societies support artificial cervical disc as an acceptable operative option.

While the Commissioner is not required in all instances to accept the IRO's recommendation, it is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO reviewer's analysis is based on extensive expertise and professional judgment. The Commissioner can discern no reason why that judgment should be rejected in the present case.

Therefore, the Commissioner accepts the findings of the IRO that the Petitioner's proposed artificial intervertebral disc replacement surgery is appropriate and medically necessary for the Petitioner and is not considered experimental or investigational.

V
ORDER

Respondent BCBSM's April 16, 2008, final adverse determination is reversed. BCBSM is required to authorize and cover the Petitioner's artificial intervertebral disc replacement surgery since it is medically necessary and not experimental for treatment of her condition. BCBSM shall authorize the Petitioner's surgery within 60 days and provide proof of the authorization to the Commissioner within seven days after the authorization is made.

Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.